

§ 872.4200

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994; 66 FR 38799, July 25, 2001]

§ 872.4200 Dental handpiece and accessories.

(a) *Identification*. A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) *Classification*. Class I.

[55 FR 48439, Nov. 20, 1990]

§ 872.4465 Gas-powered jet injector.

(a) *Identification*. A gas-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification*. Class II.

§ 872.4475 Spring-powered jet injector.

(a) *Identification*. A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification*. Class II.

§ 872.4535 Dental diamond instrument.

(a) *Identification*. A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth.

(b) *Classification*. Class I. The device is exempt from the premarket notification

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procedures in subpart E of part 807 of this chapter.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63008, Dec. 7, 1994]

§ 872.4565 Dental hand instrument.

(a) *Identification*. A dental hand instrument is a hand-held device intended to perform various tasks in general dentistry and oral surgery procedures. The device includes the operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative amalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operative explorer surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative margin finishing periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, surgical osteotome chisel, endodontic broach, dental wax carver, endodontic pulp canal file, hand instrument for calculus removal, dental depth gauge instrument, plastic dental filling instrument, dental instrument handle, surgical tissue scissors, mouth mirror, orthodontic band driver, orthodontic band pusher, orthodontic band setter, orthodontic bracket aligner, orthodontic pliers, orthodontic ligature tucking instrument, forceps, for articulation paper, forceps for dental dressing, dental matrix band, matrix retainer, dental retractor, dental retractor accessories, periodontic or endodontic irrigating syringe, and restorative or impression material syringe.

(b) *Classification*. Class I (general controls). If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures